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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/155,514 11/17/98 KAINOH

M 1102-98

HM12/0815  
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EXAMINER

SCHWADRON, R

ART UNIT

PAPER NUMBER

1644

20

DATE MAILED:

08/15/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
09/155,514

Applicant(s)  
Kainoh et al.

Examiner  
Ron Schwadron, Ph.D.

Art Unit  
1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 5/22/2001
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 2-9, 24, 25, and 45-49 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-9, 24, 25, 45-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

1. Claims 2-9,24,25,45-49 are under consideration. Claims 45-49 are newly added. Claims 1,10-23,26-44 have been cancelled. Claims 2-5,7-9,24,25 have been amended.

### RESPONSE TO APPLICANTS ARGUMENTS

2. The objection to the amendments filed 9/25/2000 (and 1/10/2000) under 35 U.S.C. 132 because it introduces new matter into the disclosure as per enunciated in the previous Office Action is withdrawn in view of applicants arguments and the Kainoh declaration filed 5/29/2001.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 24,25,45-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gallatin et al. and prior art disclosed in the specification (see references disclosed in pages 2 and 3 of specification).

Gallatin et al. teach an  $\alpha$  integrin chain extracellular domain/Ig constant domain fusion protein (see claim 19). The specification, page 11 discloses that "chimeric protein consisting of the  $\alpha$  chain of an integrin and the heavy or light chain of an immunoglobulin" actually means "the extracellular region of the  $\alpha$  chain of an integrin is bound to the constant region of the heavy chain or light chain contained an immunoglobulin". A similar definition is given for "chimeric protein consisting of the  $\beta$  chain of an integrin and the heavy or light chain of an immunoglobulin". The art recognizes that Ig constant domains are found in light or heavy chain of an Ig molecule. Regarding claims 24 and 25, the recitation of an intended use carries no weight in the instant product claims. However, Gallatin et al. does teach pharmaceutical compositions of soluble  $\alpha$

integrin (page 12). Gallatin et al. also teach integrin/Ig fusion proteins derived from a variety of known integrin molecules (see page 37, first paragraph). Gallatin et al. do not teach that the integrin/Ig fusion proteins contain the particular alpha or beta integrin chains recited in the claims. The prior art disclosed in the specification, pages 2 and 3 indicates that all of the integrin chains recited in the claims were known in the art. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Gallatin et al. teach an  $\alpha$  integrin chain extracellular domain/Ig constant domain fusion proteins, while the prior art disclosed in the specification, pages 2 and 3 indicates that all of the integrin chains recited in the claims were known in the art. One of ordinary skill in the art would have been motivated to do the aforementioned because Gallatin et al. teach integrin/Ig fusion proteins derived from a variety of known integrin molecules (see page 37, first paragraph) and that said molecules can be used in immunoassays (see page 37, first paragraph). Gallatin et al. also teach pharmaceutical compositions containing integrin/Ig fusion proteins (see page 12, first paragraph). The amino acid sequences of the Ig heavy chain and integrins recited in the claims were known in the art.

5. Claims 2-9,24,25,45-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carter et al. (US Patent 5,821,333) in view of Hori et al. (US Patent 5,916,771) and prior art disclosed in the specification (see references disclosed in pages 2 and 3 of specification).

Carter et al. teach recombinant fusion proteins containing an adhesion molecule linked to a constant heavy chain derived from an Ig molecule (see columns 19 and 20). Carter et al. teach that such molecules can be dimers, wherein the two chains contain different adhesion molecules wherein the two adhesion molecules are both fused to heavy chain Ig constant regions (see column 19, last paragraph, continued on next page). Carter et al. do not specifically teach that the adhesion molecules are derived from an  $\alpha$  and  $\beta$  chain of an integrin. Hori et al. teach that  $\beta_1$  integrin molecules were known in the art as heterodimeric molecules (see column 5). The prior art disclosed in the specification, pages 2 and 3 indicates that all of the integrin chains recited in the claims were known in the art. The prior disclosed in the specification, page 3 indicates that  $\beta_1$  integrin molecule was known in the art as heterodimeric molecule containing a  $\beta_1$  and an  $\alpha_4$  chain. Carter et al. teach that Ig fusion proteins have a variety of art recognized uses (see column 4). Hori et al. teach recombinantly produced dimeric integrin molecules (see column 5). Carter

et al. also teach recombinantly produced dimeric adhesion molecules (see columns 19 and 20). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Carter et al. teach recombinant fusion proteins containing an adhesion molecule linked to a constant heavy chain derived from an Ig molecule while Hori et al. teach that  $\beta_1$  integrin molecules were known in the art as heterodimeric molecules and that such molecules can be recombinantly produced. One of ordinary skill in the art would have been motivated to do the aforementioned because Carter et al. teach that Ig fusion proteins have a variety of art recognized uses (see column 4). Carter et al. teach use of Ig fusion proteins as drugs (see column 4). The various integrin molecules recited in the claims were all known in the art. Human Ig heavy chain sequences are known in the art (see Carter et al., columns 18 and 19).

Regarding applicants comments, Carter et al. teach recombinant fusion proteins containing an adhesion molecule linked to a constant heavy chain derived from an Ig molecule (see columns 19 and 20). Carter et al. teach that such molecules can be dimers, wherein the two chains contain different adhesion molecules wherein the two adhesion molecules are both fused to heavy chain Ig constant regions (see column 19, last paragraph, continued on next page). Carter et al. teach that immunoadhesions have a variety of art recognized uses (see column 4, third paragraph). Integrins are art known adhesion molecules. All of the integrin chains recited in the claims were known in the art. Carter et al. teach that immunoadhesins have a variety of art recognized uses for therapeutic and diagnostic purposes (see column 4, third paragraph). One of ordinary skill in the art would have been motivated to ~~do~~ have created the claimed invention in view of the cited references because Carter et al. teach that adhesion molecule/Ig fusion proteins have a variety of art recognized uses and integrins are adhesion molecules.

6. No claim is allowed.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Tuesday through Friday from 8:30 to 6:00. The examiner can also be reached on alternative Mondays. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.



RONALD B. SCHWADRON  
PRIMARY EXAMINER  
GROUP 1600 1600

Ron Schwadron, Ph.D.

Primary Examiner

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August 13, 2001